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IMPRA
A Subsidiary of C. R. Bard, Inc.
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Tempe, AZ 85280-1740
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IMPRA

510(k) Premarket Notification — CONFIDENTIAL
IMPRA Carboflo™ Vascular Grafts

510(k) Summary of Safety and Effectiveness

Submitter information	Submitter's Name:	IMPRA, Inc. A Subsidiary of C. R. Bard, Inc.
	Address:	1625 West Third Street Tempe, Arizona 85281
	Telephone:	(480) 894-9515
	Fax:	(480) 449-2546
	Contact Person:	Lorri Chavez Sr. Regulatory Affairs Specialist
	Date of Preparation:	December 23, 2000
Device name	Trade Name:	Carboflo® Vascular Graft
	Common/Usual Name:	Vascular Graft Prostheses
	Classification Name:	Vascular graft prostheses of less than 6 mm diameter
Predicate device name	Trade Name(s):	IMPRA Carboflo® ePTFE Vascular Graft
Device description	The IMPRA Carboflo® ePTFE Vascular Graft is constructed of expanded polytetrafluoroethylene (ePTFE) and contains carbon material impregnated into the inner portions of the graft walls.	
Intended use	The IMPRA Carboflo® ePTFE Vascular Graft is indicated for use as vascular prostheses.	
Technological characteristics	The IMPRA Carboflo® ePTFE Vascular Graft has the same technological characteristics as the IMPRA Carboflo® ePTFE Vascular Graft (K962639 and K964197).	

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Performance data	The IMPRA Carboflo® ePTFE Vascular Graft utilizes the same performance data as the IMPRA Carboflo® ePTFE Vascular Graft (K962639 and K964197).
Conclusion	The IMPRA Carboflo® ePTFE Vascular Graft is substantially equivalent to the currently marketed IMPRA Carboflo® ePTFE Vascular Graft (K962639 and K964197).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2001

IMPRA, Inc.
A Subsidiary of C.R. Bard, Inc.
c/o Ms. Lorrie Chavez
Sr. Regulatory Affairs Specialist
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K004011
Trade Name: IMPRA Carboflo® ePTFE Vascular Grafts
Regulatory Class: II (two)
Product Code: DSY
Dated: December 23, 2000
Received: December 27, 2000

Dear Ms. Chavez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION I-D

Statement of Indications for Use

510(k) Numbers (if known) To be assigned.

K004011

Indications for Use: IMPRA ePTFE grafts are indicated for use as vascular prostheses.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____

(Optional Format 1-2-96)

3/27/1

Division of Cardiovascular & Respiratory Devices
510(k) Number K004011